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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/442,143 11/15/99 LEVY

G 9579-14

001059 HM12/0109
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CANADA

AIR MAIL

EXAMINER

CLEMENS, K

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

01/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/442,143	Applicant(s) LEVY ET AL.	
	Examiner Karen Clemens	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 20) <input type="checkbox"/> Other: |

DETAILED ACTION
Election/Restriction

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. This Application, which contains nucleotide and amino acid sequences, is in compliance with the requirements of 37 C.F.R. 1.821-1.825.

2. The following is noted:

Groups I-VIII and XI-XIV encompass different methods using separate and distinct products. The products differ in structure and modes of action and the methods using the different products differ in the components used, the method steps employed and endpoints reached to achieve different goals and a person of ordinary skill in the art would not envision one in view of the other.

Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3-5 and 16, drawn to a method of preventing graft rejection by administration of an Fgl2 specific antibody, classified in class 424, subclass 139.1 and 152.1.
- II. Claims 1 and 16, drawn to a method of preventing graft rejection by administration of an antisense oligonucleotide to Fgl2, classified in class 514, subclass 44.
- III. Claims 2, 3-5 and 17, drawn to a method of preventing or treating fetal loss by administration of an Fgl2 specific antibody, classified in class 424, subclass 139.1 and 152.1.

- IV. Claims 2 and 17, drawn to a method of preventing or treating fetal loss by administration of an antisense oligonucleotide to Fgl2, classified in class 514, subclass 44.
- V. Claims 6 and 8, drawn to a method for diagnosing or monitoring graft rejection in an animal comprising detecting an Fgl2 protein, classified in class 435, subclass 7.1.
- VI. Claims 6 and 8 drawn to a method for diagnosing or monitoring graft rejection in an animal comprising detecting an Fgl2 nucleic acid, classified in class 435, subclass 6 and 91.2.
- VII. Claims 7-8 drawn to a method for diagnosing or monitoring fetal loss in an animal by detecting an Fgl2 protein, classified in class 435, subclass 7.1.
- VIII. Claims 7-8 drawn to a method for diagnosing or monitoring fetal loss in an animal by detecting an Fgl2 nucleic acid classified in class 435, subclass 6.
- IX. Claim 9 drawn to a method for detecting an Fgl2 protein using an antibody that binds to Fgl2 classified in class 435, subclass 7.1.
- X. Claims 10 and 11, drawn to a method for detecting an Fgl2 encoding nucleic acid molecule comprising assaying for a hybridization product and further comprising polymerase chain amplification, classified in class 435, subclass 6 and 91.2.
- XI. Claims 12-13, drawn to a method of inducing immune coagulation comprising administering a nucleic acid sequence encoding Fgl2 classified in class 514, subclass 44.
- XII. Claims 12-13, drawn to a method of inducing immune coagulation comprising administering an Fgl2 protein classified in class 514, subclass 12.
- XIII. Claims 14-15, drawn to a composition comprising an antibody specific for Fgl2 protein, classified in class 424, subclass 139.1.
- XIV. Claims 14-15, drawn to a composition comprising an antisense oligonucleotide to Fgl2, classified in class 514, subclass 44.

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XV. Claims 18-19, drawn to a vaccine comprising an Fgl2 protein or peptide classified in class 424, subclass 185.1.

XVI. Claim 20-21 drawn to an isolated nucleic acid molecule comprising an isolated nucleic acid molecule shown in Figure 4 or 8 classified in class 536, subclass 23.1.

4. The inventions are distinct, each from the other because of the following reasons:

A. Groups XIII-XVI are different products. They differ in their structure and modes of operation. They are therefore patentably distinct.

B. Groups I-XII are different methods. They differ with respect to the components used, method steps employed and endpoints to achieve different goals. Therefore, they are patentably distinct each from the other.

C. Groups XIII and I/III/V/VII/IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case the product as claimed can be used in materially different processes such as with the different methods of Groups I, III, V, VII and IX or affinity purification.

D. Groups XIV and II/IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case the product as claimed can be used in materially different processes such as with the different methods of Groups II and IV.

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5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(l).)

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Clemens whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Karen Clemens, Ph.D.
Patent Examiner
Technology Center 1600
December 22, 2000

PHILLIP GAMBEL
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PRIMARY EXAMINER
TECH CENTER 1600
12/23/00